

OCT 11 2005

K050373

**510(K) Summary of Safety and Effectiveness
(21 CFR 807.92) [21 CFR 807.87(h)]**

Unicompartmental Knee Resurfacing Prosthesis (UniCAP™)

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.87(h), this information serves as a Summary of Safety and Effectiveness for the Unicompartmental Knee Resurfacing Prosthesis (UniCAP™).

Submitted By: Arthrosurface, Inc.
28 Forge Parkway
Franklin, MA 02038
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Date: February 3, 2005

Contact Person: Steven W. Ek, Chief Operations Officer

Proprietary Name: Unicompartmental Knee Resurfacing Prosthesis
(UniCAP™)

Common Name: Knee joint femorotibial metal/polymer non-
constrained cemented prosthesis

Device Classification: Class II

Review Panel: Orthopedic

C.F.R. identification reference: 21 CFR § 888.3520 (2004)

Product Code: HSX

Indications for Use: Partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty. This device is intended to be used with bone cement.

Substantial Equivalence Information:

The Arthrosurface Unicompartmental Knee Resurfacing Prosthesis (UniCAP™) has been compared with the following legally marketed devices to which the sponsor claims substantial equivalence:

- Miller/Galante Precoat Unicompartmental Knee System (Zimmer, Inc.) (K880155)
- Link® Endo-Model™ Sled Uni-Knee System, (Link America, Inc.) (K954186)
- EUIS® Unicompartmental Knee System (Howmedica Osteonics) (K033769)
- Stelkast Unicondylar Knee System (Stelkast Co.) (K032824)

Device Description Summary

The Unicompartmental Knee Resurfacing Prosthesis (UniCAP™) incorporates a low-profile femoral articular component that mates to a taper post via a taper interlock. The femoral resurfacing component articulates against an all-polyethylene tibial resurfacing component. The UniCAP™ implants allow resurfacing of the compartment utilizing the undisturbed compartmental structures and soft-tissues.

The femoral articular component is manufactured of a Cobalt-Chromium-Molybdenum alloy per ASTM F799 and ASTM F1537. The femoral articular component has a bone contact surface that is coated with a spray-applied CP Titanium coating (identical to sponsor's previously approved devices) and a xpolished articular bearing surface.

The taper post component is a cylindrical threaded stem 20mm in length, manufactured of a Ti-6Al-4V ELI alloy per ASTM F136. The post has a tapering major and minor diameter, a full-length cannulation, and a proximal female taper bore.

The tibial resurfacing component is comprised of ultra high molecular weight polyethylene (UHMWPE) manufactured and tested to meet standards specified in ASTM D 648. The tibial component is offered in a range of thickness (6.0 mm, 6.5 mm, 7.0 mm and 7.5 mm) accommodate a variety of tibial surface conditions.

The components have been designed to allow a minimum amount of bone and soft tissue resection. The UniCAP™ system offers the surgeon a high degree of precision and flexibility in sizing and fitting the articular components to the existing anatomy.



OCT 11 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. William Ciavarra
Director, Quality Assurance & Regulatory Affairs
Arthrosurface, Inc.
28 Forge Parkway
Franklin, Massachusetts 02038

Re: K050373

Trade/Device Name: Unicompartmental Knee Resurfacing Prosthesis (UniCAP™)

Regulation Number: 21 CFR 888.3520

Regulation Name: Knee joint femorotibial metal/polymer non constrained cemented
prosthesis

Regulatory Class: II

Product Code: HSX

Dated: September 21, 2005

Received: September 22, 2005

Dear Mr. Ciavarra:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

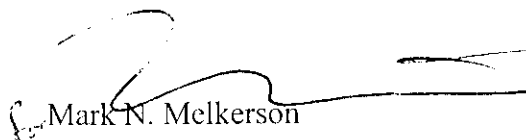
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050373

Device Name: Unicompartmental Knee Resurfacing Prosthesis (C.A.P.)™

Indications for Use:

The Unicompartmental Knee Resurfacing Prosthesis (UniCAP™) is indicated for use as a partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty. This device is intended to be used with bone cement.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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(Posted November 13, 2003)